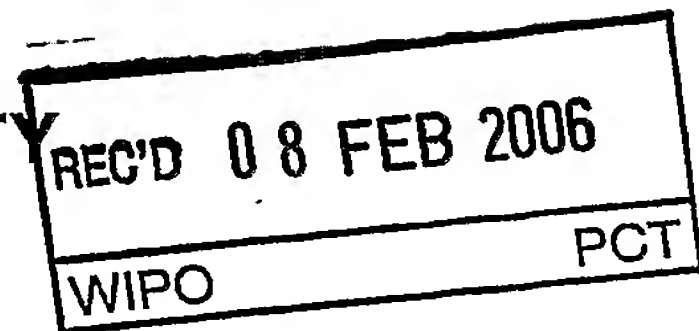



## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 2252/PCT	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB2004/005165	International filing date (day/month/year) 10.12.2004	Priority date (day/month/year) 12.12.2003
International Patent Classification (IPC) or both national classification and IPC A61M15/00, A61J7/00		
Applicant CLINICAL DESIGNS LIMITED et al. ...		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <p>I <input checked="" type="checkbox"/> Basis of the opinion</p> <p>II <input type="checkbox"/> Priority</p> <p>III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p>IV <input checked="" type="checkbox"/> Lack of unity of invention</p> <p>V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p>VI <input type="checkbox"/> Certain documents cited</p> <p>VII <input checked="" type="checkbox"/> Certain defects in the international application</p> <p>VIII <input type="checkbox"/> Certain observations on the international application</p>		
Date of submission of the demand  12.07.2005	Date of completion of this report  07.02.2006	
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Vänttinen, H  Telephone No. +49 89 2399-7442	



# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB2004/005165

## I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

### Description, Pages

1-15 as originally filed

### Claims, Numbers

1-34 as originally filed

### Drawings, Sheets

1/8-8/8 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB2004/005165

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

### III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
  - ☒ claims Nos. 34
- because:
- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
  - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
  - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
  - ☒ no international search report has been established for the said claims Nos. 34
2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:
- ☐ the written form has not been furnished or does not comply with the Standard.
  - ☐ the computer readable form has not been furnished or does not comply with the Standard.

### IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:
- ☐ restricted the claims.
  - ☐ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☐ neither restricted nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is
- ☐ complied with.

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. **PCT/GB2004/005165**

☒ not complied with for the following reasons:

**see separate sheet**

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-33 .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Yes: Claims	2-6,10-19,20-23,25-33
	No: Claims	1,7-9,19,24
Inventive step (IS)	Yes: Claims	4-6,10-19,20-23,25,27-33
	No: Claims	1-3,7-9,19,24,26
Industrial applicability (IA)	Yes: Claims	1-33
	No: Claims	

2. Citations and explanations

**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

## **1 Concerning Item IV**

The subject-matter of claim 1 does not include a counter. The dispenser according to claim 1 only has to be adapted for accommodating a counter for counting the dispensed portions of a substance. Thus, a device according to claim 1 solves the problem of dispensing a medicament and the device of claim 34 the problem of providing a reusable counter for counting medicament dispensed by a dispenser. Consequently, claims 1 and 34 do not have any common technical features and thus said claims cannot have any common or corresponding special technical features either. Hence, claims 1 and 34 lack unity. The separate inventions/groups of inventions are:

Claims 1-33: A dispenser and a method for manufacturing the same  
Claim: 34: A multi-use counter

Because the applicant has not paid the requested additional search fees, the subject-matter of claim 34 has not been searched. Consequently, the subject-matter of claim 34 cannot be examined in respect of Article 33(2)-(4) PCT.

## **2 Concerning Item V**

- 2.1 WO-A-01/37909 (D1) discloses a dispenser having a body (3), a container (4), a dispensing mechanism comprising a displaceable element (p.8, l. 15-24), an accommodation on the body (2) for a counter, and a closure (7) which co-operates with a portion of the body as defined in claim 1. In addition, also WO-A-01/31578 (D2) is considered to disclose a device which falls under the wording of claim 1. Consequently and because the subject-matter of claim 1 does not include a counter, the subject-matter of claim 1 does not meet the requirement of Article 33(2) PCT over the disclosures of D1 and D2.
- 2.2 Also the technical features of the dependent claims 7-9, 19 and 24 appear to be disclosed by D1. Thus, said claims do not meet the requirement of Article 33(2) PCT either.
- 2.3 The technical features of the dependent claims 2 and 3 appear to relate minor constructional changes which come within the scope of the customary practice followed

by persons skilled in the art, especially as the advantages thus achieved can be readily contemplated in advance. Furthermore, the subject-matter of claim 26 is considered to be obvious in the light of the disclosure of US-A-5 299 701. Consequently, the subject-matters of said claims do not appear to meet the requirement of Article 33(3) PCT.

- 2.4 The technical features of dependent claims 4-6, 10-18, 20-23, 25, and 27-31 do not appear to be derivable from any of the cited documents in an obvious manner. Thus, the subject-matters of said claims appear to meet the requirements of Article 33(2) and (3) PCT.
- 2.5 The subject-matter of independent method claim 32 is also considered to meet the requirements of Article 33(2) and (3) PCT, because the cited documents neither disclose a dispenser according to claim 11 or 16 nor the method steps defined in claim 32. Consequently, also the dependent claim 33 meets the requirements of Article 33(2) and (3) PCT.
- 2.6 The industrial applicability (Article 33(4) PCT) of a device according to the claims 1-31 and of a method according to claims 32 and 33 is self-evident.

### **3 Formal Objections**

The closest prior art (D1) has not been identified as required by Rule 5(a)(ii) PCT. Furthermore, the independent claims are not in the two-part form as required by Rule 6.3(b) PCT. In addition, the claims do not include reference signs in parentheses as required by Rule 6.2(b) PCT.